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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/707,852	11/07/2000	Andrey Zarur Jury	S1417/7004	9828

7590

07/17/2006

Timothy J Oyer  
Wolf Greenfield & Sacks PC  
600 Atlantic Avenue  
Boston, MA 02210

EXAMINER
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REDDING, DAVID A

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 07/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/707,852

Applicant(s)

JURY ET AL.

Examiner

David A. Redding

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 157-174 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 157-174 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/2/06</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 174, 157-173, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 174 it is unclear if the “inlet fluidly connectable to a source of nutrients” is the same or different from the “inlets” of the reaction units.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

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Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 174,158-160,169-171, are rejected under 35 U.S.C. 102(e) as being anticipated by WO 99/55828.

Figure 1 shows a small scale reactor (18) comprising a plastic substrate having a plurality of reaction units (6) constructed to operate in parallel, each unit comprising an inlet connected to chamber (9), an outlet connected to waste chamber (10) with a fluid pathway therebetween, the pathway including a chamber (2) having a surface suitable for cell growth and a volume less than 1ml. The reaction unit (6) includes a membrane (15) which defines a wall in the chamber (2). The membrane (15) allows fluid surrounding the cells to flow to an enclosure (3) positioned proximate the membrane (15). The reference is silent as to the chamber (2) being connected to a source of nutrients. However, the includes the same structure ((9), inlets) as the claimed invention and therefore considered to be **connectable to a source of nutrients for the cells having a controlled pH**. Further, the reference is silent as to a "product" involved in the interaction of cells passing through the membrane. Rather, the reference does disclose that the membrane allows the fluid supporting the cells to move beyond the membrane which in the examiners opinion would include cell interaction products. See page 4, lines 25 thru page 8, line 15.

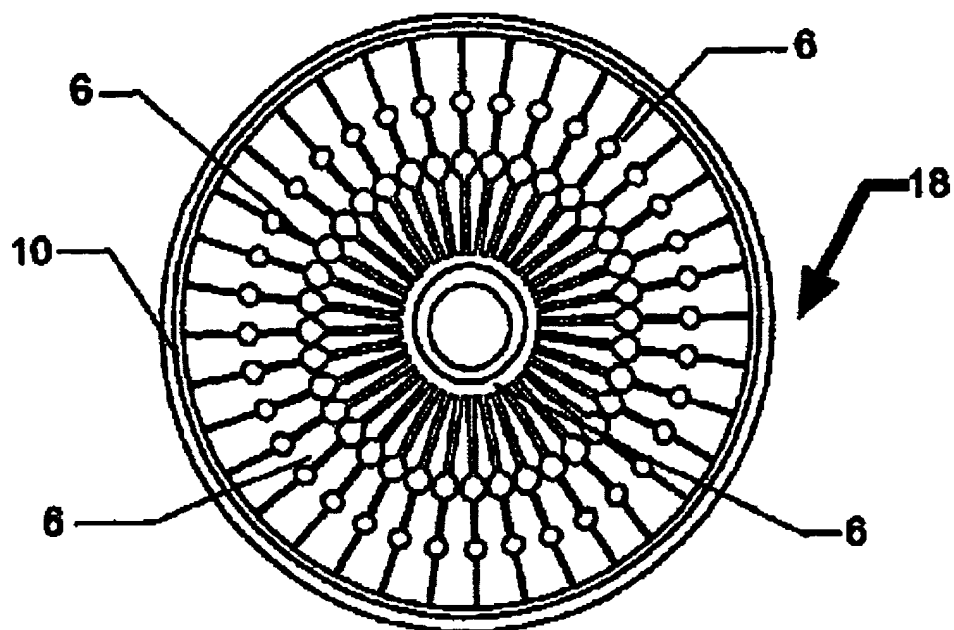


FIG. 1b

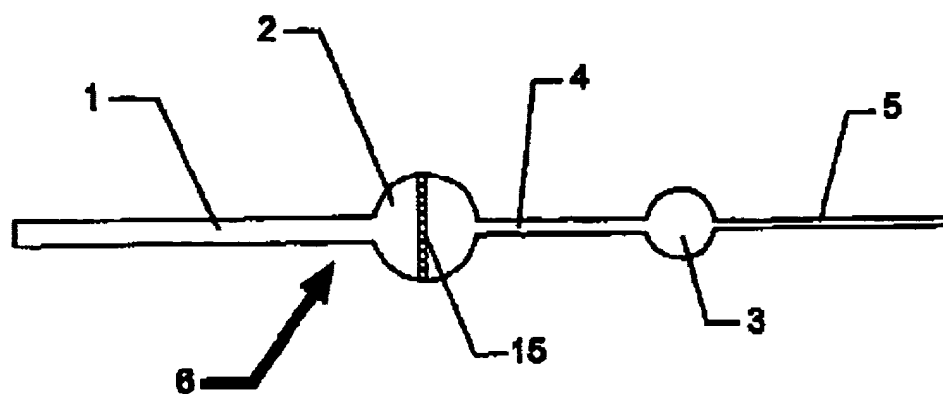
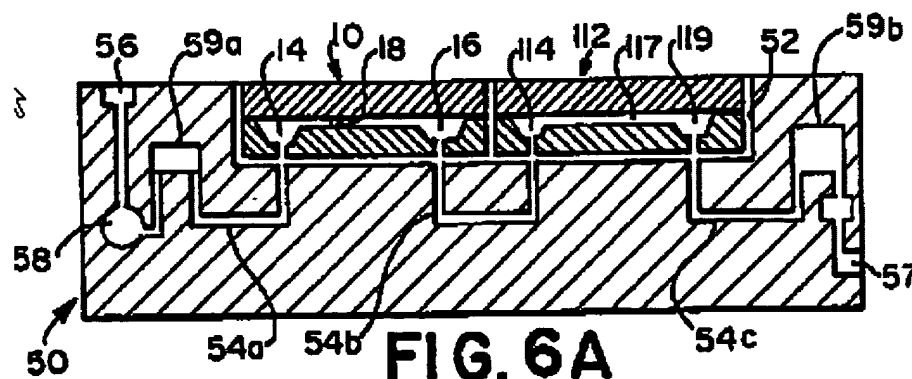


FIG. 3

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Claims 174,157-162,165,168, are rejected under 35 U.S.C. 102(e) as being anticipated by USP 6,184,029 (Wilding et al.).

Wilding et al. discloses a device comprising two reactions units (10,112), each reaction unit comprising inlets (structure leading into elements (14,114), outlets (structure leading out of elements 116,119), a fluid pathway established between the inlets and outlets of the units (10,112). The units (10,112) including at least one chamber (114,116,114,119) having a volume of less than 1ml and capable of supporting cell growth. The chambers (14,16, 114,119) being fluidly connected to an inlet (56) which is considered capable of being connected to a source of nutrients for cells having a controlled pH. One unit (10) is shown with a membrane (18) capable of operating as claimed and in flow communication with an enclosure (59b, or 57). The reference further discloses the use of pressure sensors (59a,59b), temperature sensors (95) and means for controlling temperature. See col.4, lines 1-7; col.7, line 62 thru col.8, lines 12; col. 9, lines 5-55. The device is disclosed as being comprised of plastic or glass substrate which is considered capable of supporting cells growth.



***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 169-171 are rejected under 35 U.S.C. 103(a) as being unpatentable over USP 6,184,029 B1 (Wilding et al.).

In re Harza, 274 F.2d 669, 124 USPQ 378 (CCPA 1960) the court held that mere duplication of parts has no patentable significance unless a new and unexpected result is produced.). Accordingly, in the absence of unexpected results it would have been obvious to one skilled in the art to provide the number or reaction units claimed.

***Response to Arguments***

Applicant's arguments concerning the 35 U.S.C. 112, second paragraph rejections in the Office Action mailed 2/12/06 are persuasive. Specifically applicants citation of support on page 6, lines 26-28; page 12, lines 27-31 is considered to provide the necessary support for the claim limitations previously rejected. Accordingly, the rejections have been withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Redding whose telephone number is 571-272-1276. The examiner can normally be reached on Mon.-Fri. 6:00 - 3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran-Piazza can be reached on 571-272-1224. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



David A Redding  
Primary Examiner  
Art Unit 1744

DAR